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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,800	11/06/2001	Victor Raso	BBRI-2006	7805

7590 02/24/2004
Kevin M. Farrell
One New Hampshire Avenue
Suite 350
Portsmouth, NH 03801

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,800

Applicant(s)

RASO, VICTOR

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-106 is/are pending in the application.
- 4a) Of the above claim(s) 47-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Group I, claims 37-46 in Paper No. 12 is acknowledged.

Claims 47-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

The terminal disclaimer has been considered and approved. After reviewing the previous action, the specification and applicant's arguments, it was decided that the following non-final action should be done.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification teaches that antibody 5A11 was produced by using a hapten having a statine between Phe-19 and Phe-20 or between Phe-20 and Phe-21 (Table 8). This antibody is further taught on pages 44-45 and Table 9 to solubilize a $^{125}\text{I}\beta_{1-40}$, indicating that this antibody has catalytic activity. Antibodies 6E6, 3B5 and 8E4 are taught on page 43 and Figure 15 to have catalytic activity but the hapten used to produce these antibodies is not disclosed by the specification. No other antibodies are shown to have catalytic

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activity against A β . Therefore it is maintained that the specification does not teach one of ordinary skill in the art to make catalytic antibodies using anything other than statine analogs and therefore the instant claim should be so limited.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gravina, et al. (AU) and Solomon, et al. (AX2) in view of Shin, et al. (AS), Friden (AD) and Saito, et al. (AX). Gravina, et al. teach that antibodies can be made against A β and Solomon, et al. teach an antibody against A β has been made that will "interfere with the aggregation of β -amyloid and trigger reversal to its nontoxic, normal components" (abstract). Shin, et al. and Friden, et al. teach that when an antibody to the transferrin receptor is fused to another antibody, uptake across the blood-brain barrier occurred. Saito, et al. teach that when A β was conjugated to an antibody to the rat transferrin receptor, blood-brain barrier transport was increased.

It would have been obvious to one of ordinary skill in the art to use the teachings of the two primary references that antibodies can be made --+

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against A β to make these antibodies and to use the teachings of the secondary references that an antibody to the transferrin receptor will cause or increase uptake across the blood-brain barrier to fuse or conjugate the antibodies directed against A β with antibodies against the transferrin receptor to produce a bispecific antibody that will cause the A β antibodies to be taken up across the blood-brain barrier. The motivation would have been to study the effect of these antibodies on A β in the brain. Applicant has admitted in their Remarks that the production of such bispecific antibodies are "well known in the art, and as such the production of the same is a matter of routine experimentation".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

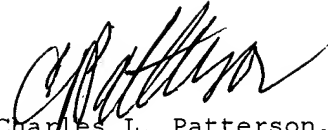
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'C. L. Patterson, Jr.', written in a cursive style.

Charles L. Patterson, Jr.
Primary Examiner
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Patterson
February 23, 2004